UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/642,242	08/17/2000	Tomas Andrysek	UD&LP049	7359

22434 7590 04/19/2002

BEYER WEAVER & THOMAS LLP
P.O. BOX 778
BERKELEY, CA 94704-0778

EXAMINER	
LUKTON, DAVID	

ART UNIT	PAPER NUMBER
1653	11

DATE MAILED: 04/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/642,242	Andrysek
Examiner	**Art Unit**
David Lukton	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 25, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above, claim(s) *1, 3-24, 26, 28, 30, and 32* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *2, 25, 27, 29, and 31* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

Pursuant to the directives of paper No. 10 (filed 1/25/02), claims 2, 25, 27, 29, 31 have been amended. Claims 1-32 remain pending. Claims 2, 25, 27, 29, 31 are examined in this Office action; claims 1, 3-24, 26, 28, 30, 32 remain withdrawn from consideration.

Applicants' arguments filed 1/25/02 have been considered and found persuasive in part. The 112, first paragraph rejection of claims 2, 25, 27, 29 is is withdrawn.

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 31 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 31 is drawn to a "pharmaceutical dosage form". The term "pharmaceutical" implies therapeutic efficacy, which is not in evidence. As indicated previously, in example 8, applicants have asserted that they have provided a "verification of biovailabiltiy". However, this assay employed the composition of example 1; the

composition of example 1, in turn, contains alcohols, which is a non-elected invention. Accordingly, example 8 does not contribute to the enablement. In addition, a "non-specific immunoassay" was used to assess cyclosporin levels. However, an immunoassay does not necessarily distinguish between hydrolyzed and non-hydrolyzed peptide; moreover, even if it is possible to increase the concentration of a given composition (containing an active agent) in blood, it is not necessarily the case that the active agent in question is more bioavailable. If it is indeed true that at a time point two hours after administration, the concentration of the composition containing cyclosporin is in fact higher than if "Neoral" was used, that does not prove that the cyclosporin will be more bioavailable to the tissues that would benefit from it. The claimed composition may affect the ability of the cyclosporin to distribute from the blood into various tissues. Thus, this experiment does not establish a therapeutic efficacy of the composition containing cyclosporin. On p. 22 a "bioequivalence study design" is described, but the compositions used are not set forth. The assumption is at this point that the claimed composition was not used. Given that applicants have not established therapeutic efficacy for any of the claimed compositions, it is suggested that the term "pharmaceutical" be deleted from line 1 of claim 31. Either of the following could be used, for example:

> *A dosage form comprising a gelatin capsule which contains a formulation according to claim 2.*

A gelatin capsule containing a formulation according to claim 2.

In the event that it is well known in the art that cyclosporin inhibits proliferation of parasites and/or HIV replication, either of the following could additionally be claimed:

A gelatin capsule containing a formulation according to claim 2, wherein cyclosporin is present in an amount effective to inhibit proliferation of parasites.

A gelatin capsule containing a formulation according to claim 2, wherein cyclosporin is present in an amount effective to inhibit replication of HIV (human infectivity virus)

Similarly, in the event that a given claim "X" were drawn to a composition in which the only "active" ingredient were taxol, the following could be used:

A gelatin capsule containing a formulation according to claim X, wherein taxol is present in an amount effective to inhibit proliferation of tumor cells.

*

Claims 25 and 29 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- In claim 25, a Markush Group is recited. The last member of the group should be preceded by the conjunction *and* rather than "or".
- Claim 29 encompasses the possibility of component "(a)" being a taxane. However, this possibility is precluded by claim 2, upon which claim 29 is dependent. Accordingly, the claim dependence is not proper. The same applies in the case of claim 27.
- Claim 29 recites that "component (a) **includes** at least one compound selected from the group **comprising** cyclosporins". First the use of either of these

open-ended terms ("includes" and "comprising") renders the claim dependence improper. Claim 2 does not state the possibility that component (a), by itself can "include" or "comprise" anything other than a cyclosporin. It is true that the overall composition of claim 2 could include other active drugs. But it is not true that part (a) of claim 2 can encompass anything other than a cyclosporin. Thus, the claim dependence is not proper. But a separate issue is that the term "comprising" in reference to a Markush Group renders the claim indefinite.

*

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 2, 25, 27, 29, 31 are rejected under 35 U.S.C. §103 as being unpatentable over Stuchlik (WO 98/10747).

Stuchlik discloses (e.g., page 4) compositions comprising cyclosporin and polyglycerol esters. The reference does not disclose the specific ratios of components. However, it

is within the capability of the ordinarilly skilled drug formulation specialist to vary dosages in order to achieve a target pharmacokinetic objective.

Thus, the claims are rendered obvious.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1600